UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: NEXIUM (ESOMEPRAZOLE) ANTITRUST LITIGATION	MDL No. 2409 Civil Action No. 1:12-md-02409
This Document Relates To: All Actions	

PLAINTIFFS' PROPOSED PRELIMINARY JURY INSTRUCTIONS FOR PHASE I OF TRIAL

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PRELIMINARY INSTRUCTIONS FOR USE AT BEGINNING OF TRIAL[1]

Plaintiffs respectfully request the following instructions be given to the jury at the outset of the trial. Plaintiffs reserve the right to submit additional proposed instructions of law.

PROPOSED JURY INSTRUCTION 1

1. The Hatch-Waxman Act

This case involves brand and generic drugs, and you will learn about how the United States Food and Drug Administration, or the "FDA," approves drugs. I am going to give you a brief explanation of the drug approval process to help you understand better the evidence that will be presented.

Federal law requires that drug companies apply for and obtain approval from the FDA before they can sell a drug in this country.[2] The first company to develop a drug files an application called a New Drug Application or "NDA."[3] The NDA contains technical information on the chemicals in the drug, the method of manufacturing it, and its effect on the human body.[4] The purpose of the New Drug Application is to demonstrate to the FDA that the drug is safe and effective for its proposed uses.[5]

If the FDA concludes after reviewing the application that the drug is both safe and effective, it approves the New Drug Application and allows the drug to be sold in the United States.[6] Drugs approved under the New Drug Application process are often called "brand-name

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[1] Plaintiffs reserve the right to supplement and amend these proposed jury instructions.

[2] Federal Food, Drug, and Cosmetics Act, 21 U.S.C. §§ 301-392.

[3] Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act"), 21 U.S.C. § 355.

[4] 21 U.S.C. § 355(b)(1).

[5] *Id.*

[6] 21 U.S.C. § 355(c)(1)(A).

drugs" because manufacturers market them under a brand name rather than under the drug's chemical name. Nexium, the prescription drug at issue in this case, is an example of a brand-name drug. The active ingredient in Nexium is a chemical called esomeprazole magnesium, which you may hear shortened to esomeprazole.

The FDA also approves generic drugs.[7] Generic drugs have the same active ingredient as the brand drug, but are usually sold under their chemical name. If you buy Tylenol, for example, you are buying the brand name version. The active ingredient in Tylenol is acetaminophen. If you buy a bottle just labeled acetaminophen, it's the generic. The same goes for prescription drugs. Nexium is the brand name; the generic is called esomeprazole or esomeprazole magnesium.

There is a federal law you will hear about that governs how generic drugs are approved. Its full name is the "Drug Price Competition and Patent Term Restoration Act of 1984," but it is more commonly called the "Hatch-Waxman Act" or simply "Hatch-Waxman."[8] The Hatch-Waxman Act covers the requirements and procedures for determining that a generic is as safe and effective as the brand drug. As suggested by its full name, Hatch-Waxman was intended in part to encourage price competition between brand and generic manufacturers.

The Hatch-Waxman Act requires that the generic drug be essentially the same as the brand-name drug: the generic drug must contain the same active chemical ingredient as the brand-name drug, must be in the same dosage form (*i.e.*, tablet or capsule) and the same dosage strength as the brand-name drug, and must be bioequivalent to the brand-name drug.[9]

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[7] 21 U.S.C. § 355(b)(1)(B).

[8] 21 U.S.C. § 355.

[9] 21 U.S.C. § 355(j)(2).

A manufacturer gets FDA approval to market a generic drug by filing an Abbreviated New Drug Application,[10] also known as an "A-N-D-A," or an "ANDA." The generic company need not demonstrate all over again that the drug is safe and effective, as the FDA has already concluded that the brand drug is safe and effective. The generic company just needs to demonstrate that the generic drug is bioequivalent to the approved brand-name drug. "Bioequivalent" means that the generic drug has the same effect in the patient's body as the brand-name drug.[11] The generic company must also prove that it can manufacture the drug to the required specifications.[12] So that is some basic background on the requirements and procedures for establishing that a generic drug is safe and effective.

The Hatch-Waxman Act also addresses how and when brand and generic drug companies can compete with each other. Brand-drug manufacturers often assert that the brand drug, or the process for making it, is covered by one or more patents. I haven't mentioned patents yet, but you will be hearing about them in this case. A patent is a legal document issued by the United States Patent and Trademark Office, or PTO, that describes an invention and allows the patent owner to file a lawsuit seeking to exclude other manufacturers from making, using, offering to sell, or selling the claimed invention within the United States.[13] If a person or entity sells something without permission and it is covered by a patent, the patent owner can sue the seller for what is called "patent infringement." The person sued has a number of potential defenses, including that the patent is invalid, that it can't be enforced for certain reasons, or that there is no infringement even if the patent is valid.

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[10] 21 U.S.C. § 355(j)(2).

[11] 21 U.S.C. § 355(j)(8)(B).

[12] 21 U.S.C. § 355(j)(2)(A)(vi).

[13] 35 U.S.C. § 271.

I will explain more about patents later. For now, you simply need to understand that brand drug manufacturers often claim that sale of a competing generic drug would infringe one or more of the brand manufacturer's patents, while generic manufacturers often claim, in response, that their generic versions of brand drugs do not infringe or that the patents are not valid or enforceable, or all of the above.

To promote these kinds of patent challenges, the Hatch-Waxman Act requires that a brand manufacturer filing a New Drug Application list all of its patents that it contends would be infringed by the sale of a competing generic.[14] The list is kept in an FDA publication called the "Orange Book"[15] because it literally has an orange cover. By putting the patents in the Orange Book, the FDA is not making any judgments about whether the patents are valid or could be infringed. The FDA simply lists the patents that the brand drug manufacturers ask it to list.[16]

When a generic manufacturer submits an ANDA seeking FDA approval to market a generic version of the brand drug, the Hatch-Waxman Act requires the generic manufacturer to make one of four certifications regarding the patents that the brand manufacturer has listed in the Orange Book concerning the drug.[17] The particular type of patent certification involved in this case is known as a "Paragraph IV Certification."[18] In a Paragraph IV Certification, the generic

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[14] 21 U.S.C. § 355(b)(1).

[15] The term "Orange Book" refers to the FDA's publication formally titled "Approved Drug Products with Therapeutic Equivalence Evaluations" and specifically its Patent and Exclusivity Information Addendum, which FDA is required to update every thirty days. 21 U.S.C. § 355(j)(7)(A).

[16] *In re Buspirone Patent & Antitrust Litig.*, 185 F. Supp. 2d 363, 371 (S.D.N.Y. 2002) ("the FDA is required by law to publish the information in the Orange Book. *See* 21 U.S.C. §§ 355(b)(1) & (c)(2) ('Upon submission of patent information under [these] subsection[s], the Secretary shall publish it.'). Hence, the FDA's actions are non-discretionary and do not reflect any decision as to the validity of the representations in an Orange Book listing.").

[17] 21 U.S.C. § 355(b)(2)(A).

[18] 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

manufacturer certifies that, although the brand manufacturer has listed certain patents in the Orange Book with respect to the brand drug, selling the generic drug before those patents expire will not infringe the patents because the patents are not valid or enforceable or simply do not cover the generic drug.[19]

Under the Hatch-Waxman Act, within 45 days after receiving notice of the Paragraph IV Certification, the brand manufacturer can bring a patent infringement lawsuit against the generic manufacturer in federal court.[20] That federal court will then decide who is right: are the patents valid and infringed, or not?

If the brand manufacturer brings a patent infringement lawsuit within 45 days, the Hatch-Waxman Act provides that the FDA cannot approve the generic drug for 30 months or until the patent lawsuit is over, whichever happens first.[21] You may hear the lawyers or witnesses referring to this as the "30-month stay" – because final FDA approval of the generic drug is "stayed" – or held up – for up to 30 months. At the end of the 30-month stay, however, the FDA may approve an ANDA even if the patent lawsuit has not ended or settled. If this happens, the generic manufacturer may choose to launch its generic product "at risk"—that is, at risk of later losing the infringement case. Losing an infringement case after launching at risk can result in significant liability for the generic manufacturer, as damages typically are calibrated by the amount of its at-risk sales.[22]

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[19] *Id.*

[20] 21 U.S.C. § 355(c)(3)(C).

[21] *Id.* If the brand company sues after 45 days, it does not get the benefit of the 30-month stay.

[22] *In re Nexium (Esomeprazole) Antitrust Litig.*, MDL No. 02409, 2014 WL 4370333 (D. Mass. Sept. 4, 2014). *See also* 35 U.S.C. § 271(e)(4)(C) (providing that damages may be awarded "only if there has been commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug"); 35 U.S.C. § 284 (providing for "damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer").

In passing the Hatch-Waxman Act, part of what Congress wanted to encourage is for generic manufacturers to challenge the validity and applicability of patents on brand drugs. Congress understood both that some brand patents are invalid and that generic companies can develop generics that do not infringe the patents even if they are valid. Congress wanted to give generic drug companies a financial incentive to do the work needed to challenge brand drug patents and demonstrate that they are invalid, or invent around them, which means developing a generic that does not infringe.[23] So Congress created a kind of reward to encourage generic manufacturers to challenge brand patents.[24]

You will hear the lawyers and witnesses refer to this reward as the "180-day exclusivity." Here is how it works: the first generic manufacturer that files a Paragraph IV Certification with respect to a particular brand drug can get a period of 180 days (six months) as the only ANDA-approved version of that drug on the market.[25] The Hatch-Waxman Act prohibits the FDA from granting approval of any other manufacturer's ANDA for that drug until 180 days after the first generic manufacturer that filed a Paragraph IV Certification enters the market.[26]

This 180-day period of exclusivity can be very valuable. In some cases, it can even be worth hundreds of millions of dollars, depending on the sales of the corresponding brand drug.[27] The reason that the generic company often can earn so much during a six-month period of exclusivity is that a generic company with 180 days of exclusivity will be the only generic on the market for six months and, during that time, it will get all of the generic sales. As a result, it will

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[23] H.R. REP. NO. 98-857, pt. 1, at 14-15 (1984) *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647.

[24] *Id.*

[25] 21 U.S.C. § 355(j)(5)(B)(iv)(I).

[26] *Id.*

[27] *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2229 (2013) ("[T]his 180-day period of exclusivity can prove valuable, [potentially] worth several hundred million dollars.'").

generally be able to charge a higher price for its generic product during the period of exclusivity than if it had to compete against other generic manufactures. You'll hear testimony about how competition from additional generics can lower prices, but for now it is sufficient to understand why those six months can matter so much.

The first Paragraph IV filer gets this 180-day exclusivity regardless of when it enters the market: the first-filer gets the 180-day exclusivity if the 30-month stay expires and it launches; it gets the exclusivity if it does not launch but waits until after the court decides the patent case; and in many circumstances it gets the 180-day exclusivity even if it settles the patent case rather than winning it at trial.[28]

When I just described the 180-day exclusivity, I was very careful to say that it only prevents the FDA from granting approval to any other manufacturer's *ANDA* during that period. The 180-day exclusivity does *not* apply to the brand company itself. The brand company can keep selling its own brand drug during the 180 day period and afterwards. A brand company can also decide to sell what is called an "authorized generic."[29] An authorized generic is the brand drug, sold by the brand company or by another company that the brand company authorizes, but with a generic label and usually at generic prices. The brand can sell an authorized generic whenever it wishes to, but it usually does not start selling one until a competing generic company is ready to launch its generic. The reason is that if the brand company launched the authorized generic before it faced competition, the brand company would just be taking branded sales from itself.

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[28] 21 U.S.C. § 355(j)(5)(B)(iv)(I). *See also In re Nexium (Esomeprazole) Antitrust Litig*., MDL No. 02409, 2014 WL 4370333, at *6 (D. Mass. Sept. 4, 2014) ("Because no other manufacturer may launch a product until 180 days after the first filer has done so, a first filer's delay effectively delays all of its competitors' entries, creating a bottleneck in the market that postpones the date on which any generic product will become available.").

[29] *Teva Pharm. Indus. v. FDA*, 410 F.3d 51, 54 (D.C. Cir. 2005); 21 U.S.C. § 355(t)(3).

You will hear testimony regarding other aspects of this 180-day exclusivity – for example, under certain circumstances the Paragraph IV first-filer might in effect transfer that exclusivity right to another generic manufacturer.[30] The Paragraph IV first-filer may also give up or "relinquish" its exclusivity; once the 180-day exclusivity is relinquished, it is no longer a barrier preventing other generic applicants from obtaining final approval.[31]

[30] Letter from William K. Hubbard, Associate Commissioner for Policy and Planning, FDA, to Bert W. Rein, Wiley Rein & Fielding LLP (Jul. 2, 2004) (responding to Citizen Petition at Docket No. 2004P-0227), *available at* http://www.regulations.gov/#!documentDetail;D=FDA-2004-P-0014-0002 (follow "View Attachment" hyperlink)

[31] *Id.* at 4-5.

PROPOSED JURY INSTRUCTION 2

2. Patents

I want to tell you a bit more about patents. As I mentioned, a patent is a legal document issued by the PTO that describes an invention and allows the patent owner to file a lawsuit seeking to exclude other manufacturers from making, using, offering to sell, or selling the claimed invention within the United States without the patent owner's permission.[32] If a court finds a patent to be "valid" and "infringed" – concepts that I will address in a moment – the court can order the infringer not to make, use, or sell the invention,[33] or it can award damages to the patent holder if the infringer has already begun making, using, or selling the invention.[34] If, however, the court finds the patent invalid or not infringed, the patent holder is not entitled to damages or to keep the accused product out of the market.

To get a patent, an applicant files an application with the PTO. The application includes what is called a "specification," which contains a written description of the alleged invention explaining what the alleged invention is, how it works, how to make it, and how to use it.[35] The specification concludes with one or more numbered sentences that are called patent "claims."[36] If the PTO eventually grants a patent to the applicant, the claims at the end of the patent define the boundaries of its protection and give notice to the public of those boundaries.[37]

Employees of the PTO called "patent examiners" review all patent applications to determine whether or not the claims are appropriate for patent protection – whether the claimed

[32] 35 U.S.C. § 271; 35 U.S.C. § 2.

[33] 35 U.S.C. § 283.

[34] 35 U.S.C. § 284.

[35] 35 U.S.C. § 112.

[36] 35 U.S.C. § 112(b).

[37] *Id.*

invention is, for example, truly new – and whether or not the specification adequately describes the invention claimed.[38]

After evaluating the application,[39] the examiner informs the applicant in writing of what the examiner has found and whether the examiner considers any claim to be patentable and, thus, "allowed." If the examiner instead "rejects" the claims,[40] the applicant has an opportunity to respond to the examiner to try to persuade the examiner to allow the claims as stated, to change the claims or to submit new claims.[41] This process may go back and forth for some time until the examiner concludes either that the application meets the requirements for a patent and the PTO should issue the patent, or that the application does not meet the requirements and the PTO should not issue the patent.[42]

When the patent applicant is trying to convince the examiner to issue the patent, no one is there at the patent office opposing the applicant. It's not like here in court, where you will hear lawyers and witnesses for both sides. When the patent office is looking at a patent application, there is no one there arguing that the PTO should not issue the patent because the claimed invention is not really new or for some other reason. The process is conducted without an adversary presenting arguments against what the applicant is asserting.[43]

Because of this, Congress provided in the patent statute that a patent issued by the PTO can subsequently be challenged in federal court. And in a court, there is an adversary who can present the other side of the argument, which can be an argument not presented to the

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[38] 35 U.S.C. § 271; 35 U.S.C. § 102.

[39] 37 CFR 1.104(a)(1); Manual of Patent Examining Procedure ("MPEP") §§ 704.01, 707(a)(1).

[40] 35 U.S.C. § 132; MPEP § 704.01(c).

[41] 35 U.S.C. § 132.

[42] 37 CFR 1.104(a)(1); MPEP § 707(a)(1).

[43] 37 CFR § 1.902-1.997 (providing for *inter partes* review of patents only post-issuance).

examiner.[44] A patent owner who wants to enforce its patent against competitors or others can also bring a lawsuit in federal court to enforce the patent.[45] In patent-enforcement lawsuits, the patent owner must prove that the patent claims cover the accused activity or product.[46] When the patent claims cover the accused activity or product, this is called "infringement."[47]

To carry its burden of proving infringement, the patent owner must prove that each aspect of the asserted patent claim is present in the accused product or process.[48] For example, if the patent claims an invention consisting of elements 1, 2, 3, 4, and 5, the accused product does not infringe if it has only elements 1, 2, 3, and 4.[49] If even a single aspect of the patent claim is missing from the accused product or process, there is no infringement of that claim and the patent owner loses the lawsuit with respect to that claim.[50] A person accused of infringement has the right to present evidence, including expert evidence, to establish that the patent claim does not in fact cover the accused product and that it therefore does not infringe the patent.[51]

If the patent owner carries its burden of proving infringement of one or more of the patent's claims, the accused infringer can still win the patent case by proving that the patent claim is invalid.[52] Patents can be shown to be invalid. Examiners are human and sometimes make mistakes or fail to uncover or appreciate the significance of the technology that existed

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[44] 35 U.S.C. § 281; 28 U.S.C. § 1338.

[45] *Id.*

[46] *Under Sea Industries, Inc. v. Dacor Corp.*, 833 F. 2d 1551, 1557 (Fed. Cir. 1987) ("The burden always is on the patentee to show infringement").

[47] 35 U.S.C. § 271(a).

[48] *Pennwalt Corp. v. Durand-Wayland, Inc.*, 833 F.2d 931, 935-36 (Fed. Cir. 1987) (en banc), *overruled on other grounds, Cardinal Chem. Co. v. Morton Intern., Inc.*, 508 U.S. 83 (1993).

[49] *Id.*

[50] *Id.*

[51] 35 U. S. C. §282(b)(1).

[52] 35 U. S. C. §282(b)(2).

before the applicant's claimed invention. Sometimes the law changes such that the legal standards applied by the examiner are different from the legal standard applied in court. Also, while only the applicant appears before the PTO when applying for a patent, accused infringers have the right to present evidence in court, including expert evidence, to establish that the alleged invention does not meet the relevant requirements and therefore the patent claims are invalid.

If the patent owner proves infringement and the accused infringer fails to prove that the patent is invalid, then the patent owner wins the patent lawsuit.[53] If, however, the patent owner fails to prove infringement and/or the accused infringer succeeds in proving the patent invalid, then the accused infringer wins the lawsuit. In that event, the accused infringer can begin selling the product (or continue selling it) without any risk of owing damages to the patent owner. Also, if the accused infringer gets a ruling from the federal court that the patent is invalid, that ruling applies in favor of everyone against whom the patent owner might try to assert it.[54] In other words, the patent is deemed to be invalid against not just the accused infringer who won the particular lawsuit, but against everyone.[55] The patent is invalid – period.

These basic principles of patent law work together with the specific Hatch-Waxman Act provisions that I already described to you. For example, recall these specific provisions of the Hatch-Waxman Act: (1) that are applicable to the pharmaceutical patents that are in the background of this antitrust case: the brand manufacturer must list the relevant patents in the Orange Book;[56] (2) the generic manufacturer can file a Paragraph IV Certification with respect to

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[53] 35 U.S.C. § 282.

[54] *Blonder-Tongue Lab. v. Univ. of Ill. Found.*, 402 U.S. 313, 350 (1971).

[55] *Id.*

[56] 21 U.S.C. § 355(b)(1).

them;[57] (3) the brand manufacturer can get an automatic 30-month stay preventing the generic from entering the market by suing the generic within 45 days;[58] (4) the generic manufacturer can enter the market after the 30 months; (5) the first generic manufacturer to file a Paragraph IV Certification can get the 180-day ANDA exclusivity; (6) and the 180-day exclusivity cannot stop a brand company from selling its own authorized generic at any time.[59]

Within this specific framework, the general patent principles that I have just outlined apply: the PTO issues patents without any advocate on the other side; to enforce the patent, the patent owner can bring a lawsuit in federal court where the patent is subject to challenge;[60] in that lawsuit the patent owner has the burden of proving infringement;[61] the accused infringer can try to prove that the patent is invalid;[62] if the patent owner wins, it can ask the court to prevent the accused infringer from making, using, or selling the product and, if the accused infringer has already entered the market, can ask for damages; if the accused infringer wins, it can enter (or continue) in the market without any risk of patent damages; and if the accused infringer wins by proving that the patent is invalid, that finding of invalidity benefits everyone who wants to make, use, or sell the product.[63]

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[57] 21 U.S.C. § 355(b)(2)(A); 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

[58] 21 U.S.C. § 355(c)(3)(C).

[59] 21 U.S.C. § 355(j)(5)(B)(iv)(I).

[60] 35 U.S.C. § 281; 28 U.S.C. § 1338.

[61] *Under Sea Industries, Inc. v. Dacor Corp*., 833 F. 2d 1551, 1557.

[62] 35 U. S. C. §282(b)(2).

[63] *Blonder-Tongue Lab. v. Univ. of Ill. Found*., 402 U.S. 313, 350 (1971).

PROPOSED JURY INSTRUCTION 3

3. Settlement of Pharmaceutical Patent Infringement Litigation

Specific to this case, the patents that AstraZeneca listed as covering Nexium "may or may not be valid, and may or may not be infringed. A valid patent excludes all except its owner from the use of the protected process or product. And that exclusion may permit the patent owner to charge a higher-than-competitive price for the patented product. But an invalidated patent carries with it no such right. And even a valid patent confers no right to exclude products or processes that do not actually infringe."[64]

The defendants in this action are AstraZeneca, Ranbaxy, Teva, Dr. Reddy's, and various corporate affiliates of these companies. Ranbaxy, Teva and Dr. Reddy's may also be referred to as the "Generic Defendants" because these companies are in the business of selling generic drugs. You may also hear Dr. Reddy's referred to as "DRL."

You will hear evidence in this case that AstraZeneca settled patent cases that it filed against Ranbaxy, Teva and Dr. Reddy's alleging infringement of patents that allegedly claimed Nexium. Plaintiffs here are purchasers of Nexium and are, broadly speaking, alleging that all four defendants violated the antitrust laws by these settlements. "Antitrust" refers to competition, and so alleging that a defendant has violated the antitrust laws means that they are alleged to have harmed competition. I will explain more about this later, but for now, you should understand that patent related settlements can sometimes violate the antitrust laws.[65]

[64] *Actavis*, 133 S. Ct. at 2231 (citations, emphases, and original alterations omitted).

[65] *Actavis*, 133 S. Ct. at 2232.

Dated: October 14, 2014

Respectfully submitted,

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I, Thomas M. Sobol, hereby certify that I caused a copy of the foregoing document to be filed electronically via the Court's electronic filing system. Those attorneys who are registered with the Court's electronic filing system may access these filings through the Court's system, and notice of these filings will be sent to these parties by operation of the Court's electronic filing system.

Dated: October 14, 2014

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